SENATE BILL No. 1174

Introduced by Senator Polanco

February 23, 2001

An act to amend Sections 1206.5 and 1241 of the Business and Professions Code, relating to clinical laboratory technology.

LEGISLATIVE COUNSEL'S DIGEST

SB 1174, as introduced, Polanco. Clinical laboratory technology: performance of blood glucose tests by certified emergency medical technicians.

Existing law provides for the regulation by the State Department of Health Services of clinical laboratories and of persons performing clinical laboratory tests or examinations or engaging in clinical laboratory practice, subject to designated exceptions.

This bill would exempt from this regulation certified medical technicians providing basic life support services or advanced support services who perform blood glucose tests.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1206.5 of the Business and Professions Code is amended to read:

1206.5. (a) Notwithstanding subdivision (b) of Section 1206 *and except as otherwise provided in Section 1241*, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section

1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist ~~when~~ *if* the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant ~~when~~ *if* authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A person licensed under Chapter 6.5 (commencing with Section 2840).

(8) A perfusionist ~~when~~ *if* authorized by and performed in compliance with Section 2590.

(9) A respiratory care practitioner ~~when~~ *if* authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(10) A medical assistant, as defined in Section 2069, ~~when~~ *if* the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.

(11) A pharmacist, ~~when~~ *if* ordering drug therapy-related laboratory tests in compliance with clause (ii) of subparagraph (A) of paragraph (5) of ~~subdivision (a) of~~, or ~~paragraph (6)~~ *subparagraph (B) of paragraph (4)* of, subdivision (a) of~~,~~ Section 4052.

(12) Other health care personnel providing direct patient care.

(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as

described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist ~~when~~ *if* the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant ~~when~~ *if* authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A perfusionist ~~when~~ *if* authorized by and performed in compliance with Section 2590.

(8) A respiratory care practitioner ~~when~~ *if* authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(9) A person performing nuclear medicine technology ~~when~~ *if* authorized by and performed in compliance with Article 6 (commencing with Section 107115) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(10) Any person ~~when~~ *if* performing blood gas analysis in compliance with Section 1245.

(11) (A) A person certified as an ‘‘Emergency Medical Technician II’’ or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840) of Division 2, or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5 of Division 2, or certified by the department pursuant to Division 5 (commencing with Section

70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, ~~so long as~~ *if* the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.

(B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a "preceptor program" means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.

(12) Any other person within a physician office laboratory ~~when~~ *if* the test is performed under the supervision of the patient's physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(13) A pharmacist, ~~when~~ *if* ordering drug therapy-related laboratory tests in compliance with clause (ii) of subparagraph (A) of paragraph (5) of ~~subdivision (a) of~~, or ~~paragraph (6)~~ *subparagraph (B) of paragraph (4)* of, subdivision (a) of~~,~~ Section 4052.

(c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and

administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist ~~when~~ *if* the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory ~~when~~ *if* the test or examination is within a specialty or subspecialty authorized by the person's licensure.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code ~~when~~ *if* the test or examination is within a specialty or subspecialty authorized by the person's certification.

(5) A licensed physician assistant ~~when~~ *if* authorized by a supervising physician and surgeon in accordance with Section 3502 or Section 3535.

(6) A perfusionist ~~when~~ *if* authorized by and performed in compliance with Section 2590.

(7) A respiratory care practitioner ~~when~~ *if* authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(8) A person performing nuclear medicine technology ~~when~~ *if* authorized by and performed in compliance with Article 6 (commencing with Section 107115) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(9) Any person ~~when~~ *if* performing blood gas analysis in compliance with Section 1245.

(10) Any other person within a physician office laboratory ~~when~~ *if* the test is performed under the onsite supervision of the patient's physician and surgeon or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(d) Clinical laboratory examinations classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:

(1) A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.

(2) A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.

(3) A licensed dentist using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

SEC. 2. Section 1241 of the Business and Professions Code is amended to read:

1241. (a) This chapter applies to all clinical laboratories in California or receiving biological specimens originating in California for the purpose of performing a clinical laboratory test or examination, and to all persons performing clinical laboratory tests or examinations or engaging in clinical laboratory practice in California or on biological specimens originating in California, except as provided in subdivision (b).

(b) This chapter shall not apply to any of the following clinical laboratories, or to persons performing clinical laboratory tests or examinations in any of the following clinical laboratories:

(1) Those owned and operated by the United States of America, or any department, agency, or official thereof acting in his or her official capacity to the extent that the Secretary of the federal Department of Health and Human Services has modified the application of CLIA requirements to those laboratories.

(2) Public health laboratories, as defined in Section 1206.

(3) Those that perform clinical laboratory tests or examinations for forensic purposes only.

(4) Those that perform clinical laboratory tests or examinations for research and teaching purposes only and do not report or use patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or for the assessment of the health of, an individual.

(5) Those that perform clinical laboratory tests or examinations certified by the National Institutes on Drug Abuse only for those certified tests or examinations. However, all other clinical laboratory tests or examinations conducted by the laboratory are subject to this chapter.

(6) Those that register with the State Department of Health Services pursuant to subdivision (c) to perform blood glucose testing for the purposes of monitoring a minor child diagnosed with diabetes ~~when~~ *if* the person performing the test has been entrusted with the care and control of the child by the child's parent or legal guardian and provided that all of the following occur:

(A) The blood glucose monitoring test is performed with a blood glucose monitoring instrument that has been approved by the federal Food and Drug Administration for sale over the counter to the public without a prescription.

(B) The person has been provided written instructions by the child's health care provider or an agent of the child's health care provider in accordance with the manufacturer's instructions on the proper use of the monitoring instrument and the handling of any lancets, test strips, cotton balls, or other items used during the process of conducting a blood glucose test.

(C) The person, receiving written authorization from the minor's parent or legal guardian, complies with written instructions from the child's health care provider, or an agent of the child's health care provider, regarding the performance of the test and the operation of the blood glucose monitoring instrument, including how to determine if the results are within the normal or therapeutic range for the child, and any restriction on activities or diet that may be necessary.

(D) The person complies with specific written instructions from the child's health care provider or an agent of the child's health care provider regarding the identification of symptoms of hypoglycemia or hyperglycemia, and actions to be taken when

results are not within the normal or therapeutic range for the child. The instructions shall also contain the telephone number of the child's health care provider and the telephone number of the child's parent or legal guardian.

(E) The person records the results of the blood glucose tests and provides them to the child's parent or legal guardian on a daily basis.

(F) The person complies with universal precautions when performing the testing and posts a list of the universal precautions in a prominent place within the proximity where the test is conducted.

(7) Those individuals who perform clinical laboratory tests or examinations, approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, on their own bodies or on their minor children or legal wards.

(8) Those certified emergency medical technicians providing basic life support services or advanced life support services as defined in Section 1797.52 of the Health and Safety Code who perform only blood glucose tests that are classified as waived clinical laboratory tests under CLIA, if the provider of those ambulance services obtains a valid certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations.

(c) Any place where blood glucose testing is performed pursuant to paragraph (6) of subdivision (b) shall register by notifying the State Department of Health Services in writing no later than 30 days after testing has commenced. Registrants pursuant to this subdivision shall not be required to pay any registration or renewal fees nor shall they be subject to routine inspection by the State Department of Health Services.

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